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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
| 08/817,547      | 03/27/97    | ADERMANN             | K 07856-0007        |

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EXAMINER

KEMMERER, E

ART UNIT  PAPER NUMBER

1646

12

DATE MAILED: 08/13/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

|                              |  |  |
|------------------------------|--|--|
| <b>Office Action Summary</b> | Application No.<br><b>08/817,547</b>     | Applicant(s)<br><b>Adermann et al.</b> |
|                              | Examiner<br><b>Elizabeth C. Kemmerer</b> | Group Art Unit<br><b>1646</b>          |

Responsive to communication(s) filed on 3/27/97, 2/15/98, 3/27/98, and 5/29/98

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 3-6 is/are pending in the application.

Of the above, claim(s) 6 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 3-5 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims 3-6 are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election of Group II (claims 3-5) in Paper No. 11 (29 May 1998) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant requests that the restriction be reviewed because of a problem in claim numbering. The application was filed with original claims 1-5. In the preliminary amendment filed 27 March 1997, claims 1 and 2 were canceled, and a new claim 7 was submitted. Since there was no original claim 6, submitted claim 7 was renumbered under 37 CFR 1.126 as claim 6. Upon review of the restriction requirement (Paper No. 9, 24 April 1998), it is deemed that claims 3-5 and 6 were restricted correctly, using the correct claim numbering. If Applicant has any questions regarding the new claim numbering, he/she is invited to contact the Examiner at the numbers below.

### ***Status of Application, Amendments, And/Or Claims***

The preliminary amendment filed 27 March 1997 (Paper No. 3) has been entered in part. As discussed above, newly submitted claim 7 was renumbered under 37 CFR 1.126 as claim 6. The requested amendments to claims 3-6 could not be entered because the cue words do not appear in the claims.

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The sequence submitted 27 March 1998 (Paper No. 8) has been entered after minor correction by the Scientific and Technical Information Center staff. Specifically, the current application data section was altered to correctly identify the current U.S. Patent Application Serial No. 08/817,547.

***Priority***

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 371 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78). In cases when the earlier application was filed under PCT, the reference must contain a statement of how the instant application is related to the PCT application. For example, in the instant application, a statement such as "This application is a national stage application of PCT..." or "This application was filed under 35 U.S.C. § 371 from PCT ..."

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Sequence Rules***

The instant application is not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not

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accompanied by the required reference to the relevant sequence identifier (i.e., SEQ ID NO:). This occurs at pp. 3-5. Compliance with the sequence rules is required.

### ***Claim Objections***

Claims 3-5 are objected to because of the following informalities: the claims depend from a canceled claim. In the interest of compact prosecution, the claims will be interpreted as depending from claim 6. However, this interpretation of the claims does not relieve Applicant from the requirement to respond to this objection. Appropriate correction is required.

### ***35 U.S.C. §§ 101 and 112, Second Paragraph***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is provides for the use of peptides, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claim 5 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 3-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites "per se known immunization" without specifying which known techniques are intended. It is suggested that the phrase "per se known" be deleted. Claims 3 and 5 recite diagnostic agent or diagnosis without referring to what disease or condition is to be diagnosed. Thus, the metes and bounds of the claims cannot be determined. Claims 3 and 4 recite agents or antibodies which "can be" produced by a particular process. It is not clear if the process is a positive limitation of the claims.

#### ***35 U.S.C. § 112, First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 3-5 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for antibodies or raised against the peptides recited in claim 6 or fragments of said antibodies which bind said peptides, and methods of detecting hPTH peptides comprising contacting a sample with said antibodies or fragments and assaying for binding, does not reasonably provide enablement for the claimed diagnostic agents or use of peptides for producing diagnostic agents. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to (3) diagnostic agents which can be obtained by immunizing an animal with at least one of the peptides of claim 6 (identical to the peptides recited in original claim 1, now canceled) obtaining immunoglobulins from said animal, and isolating fractions containing antibodies against said at least one peptide; (4) antibodies or fragments of antibodies which can be obtained by immunizing animals with said at least one peptide; and (5) use of said peptides for producing an agent for the diagnosis of biologically active hPTH(1-37). The specification discloses several specific fragments of hPTH, and states that antibodies can be prepared against these peptides which apparently recognize active hPTH fragments (such as hPTH(1-37)) and not inactive hPTH peptides (such as hPTH(1-84)), although this is not perfectly clear. The specification provides general methods for making such peptides and antibodies. The scope of patent protection sought by Applicant as defined by the claims fails to bear a reasonable correlation with the scope of enabling disclosure set forth in the specification for the following reasons. First, it is clear that the specification is enabling for antibodies or raised against the peptides recited in claim 6 or fragments

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of said antibodies which bind said peptides, and methods of detecting hPTH peptides comprising contacting a sample with said antibodies or fragments and assaying for binding, as such antibody production and detection assays are routine. However, there is a lack of direction/guidance presented in the specification regarding particular antibodies which recognize active hPTH peptide fragments and not inactive hPTH peptide fragments. It is also hard to theorize how such antibodies would identify one and not the other. For example, the disclosed peptides hPTH(1-10), hPTH(2-9), etc., disclosed at pp. 3-5 are all comprised within the inactive hPTH(1-84). If an antibody recognized an epitope in one of these short fragments, it would also reasonably be expected to recognize the longer peptide in which the epitope is comprised. Furthermore, there is an absence of working examples directed to such antibodies. The nature of the invention is complex, given the complexity of antibody structure, antibody-epitope interaction, and prediction of protein folding structure. The prior art indicates that algorithms designed to identify epitopes have proven unpredictable, with algorithms both identifying sequences as epitopes which did not prove to be so, and also failing to identify true epitopes (see Daniel et al.). Finally, the breadth of the claims is large, considering claims 3 and 5 do not specify that the agents are even antibodies, and claim 4 does not require that the antibodies or fragments bind the peptides. For all of these reasons, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3-5 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Nussbaum et al. (1982, Chemical Abstracts 96(5), Abstract No. 29060) or Tampe et al. (1992, J. Immunoassay 13(1):1-13).

For the purposes of this rejection, "diagnostic agent" is interpreted as being an agent that binds hPTH(1-37), and "diagnosis of hPTH(1-37)" is interpreted as detection of hPTH(1-37). Also, it is noted that the claims do not require that the antibodies or diagnostic agents bind active hPTH fragments while at the same time not bind inactive hPTH fragments.

Nussbaum et al. teach an antibody which binds a hPTH epitope defined as hPTH(25-34). Although the antibodies were raised against hPTH(1-34) and not raised against hPTH(25-34), one of ordinary skill in this art would reasonably have expected that the antibody disclosed by Nussbaum et al. would have had the same properties as an antibody raised against hPTH(25-34), since this is the epitope the antibody recognized. Also, the method of making the claimed diagnostic agents and antibodies does not appear to confer a unique characteristic upon the diagnostic agents or antibodies. Nussbaum et al. also teach that the disclosed antibody was used to detect biologically active hPTH(1-34).

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Tampe et al. teach antibodies which bind several hPTH epitopes including hPTH(24-30) and hPTH(12-19) (p. 5), each of which are only one amino acid residue different from the instantly disclosed hPTH(24-29), hPTH(24-31), and hPTH(12-18). The antibodies of Tampe et al. would reasonably be expected by one of ordinary skill in the art to be indistinguishable from those of the instant claims, given the nearly identical epitopes. Also, although the antibodies were raised against hPTH(1-34) and not raised against the shorter hPTH fragments, one of ordinary skill in this art would reasonably have expected that the antibody disclosed by Tampe et al. would have had the same properties as an antibody raised against the shorter hPTH fragments, since these were the epitopes the antibody recognized. Also, the method of making the claimed diagnostic agents and antibodies does not appear to confer a unique characteristic upon the diagnostic agents or antibodies. Finally, Tampe et al. also teach that the disclosed antibodies were used to detect biologically active hPTH(1-34).

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lila Feisee, can be reached on (703) 308-2731.

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Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

ECK  
August 11, 1998